

510(k) Summary
Spinal Elements Buttress Plate System

510(k) Number K081418 (pg 1 of 1)

JUL 14 2008

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-0121

Contact Information: Kerri DiMartino
Regulatory Affairs Specialist
Spinal Elements, Inc.
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Carlsbad, CA 92010
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Date Prepared: May 19, 2008

Device Identification

Proprietary Name	Spinal Elements Buttress Plate System
Common Name	Spinal Intervertebral Body Fixation Orthosis
Device Classification	21 CFR 888.3060: Appliance, Fixation, Spinal, Intervertebral Body
Proposed Regulatory Class	Class II
Device Product Code	KWQ

Device Description

The Spinal Elements Buttress Plate System is comprised of plates and screws that are used for attachment to the anterior lumbar spine. Both plates and screws are available in a variety of sizes to suit the individual pathology and anatomic condition of the patient. Plates and screws are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3.

Intended Use of the Device

The Spinal Elements Buttress Plate System is intended for anterior intravertebral body screw fixation/attachment to one vertebral body of the L1-S1 spine, extending over the adjacent intervertebral space to stabilize and buttress bone grafts/intervertebral body fusion devices following reconstruction for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The system is intended to be used in skeletally mature patients in conjunction with traditional fixation and is not intended for load bearing applications.

Substantial Equivalence

The Spinal Elements Buttress Plate System is substantially equivalent to predicates, K2M Cayman Buttress Plate System (K080302) and the Synthes TiLPS (K970048), in regard to indications for use, material, general design features, and function.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spinal Elements, Inc.
% Ms. Kerri DiMartino
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010

JUL 14 2008

Re: K081418
Trade/Device Name: Spinal Elements Buttress Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 19, 2008
Received: May 20, 2008

Dear Ms. DiMartino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081418

Device Name: Spinal Elements Buttress Plate System

Indications for Use:

The Spinal Elements Buttress Plate System is intended for anterior intravertebral body screw fixation/attachment to one vertebral body of the L1-S1 spine, extending over the adjacent intervertebral space to stabilize and buttress bone grafts/intervertebral body fusion devices following reconstruction for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The system is intended to be used in skeletally mature patients in conjunction with traditional fixation and is not intended for load bearing applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

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Division of General, Restorative,
and Neurological Devices

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